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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,683	08/18/2003	James Robert Swartz	STAN-273	4598

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EXAMINER	
VOGEL, NANCY S	
ART UNIT	PAPER NUMBER
1636	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,683	SWARTZ ET AL.	
	Examiner	Art Unit	
	Nancy T. Vogel	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-7,13 and 23-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-7, 13 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/20/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 4-7, 13, 23-25 are pending in the case.

Receipt of the Information Disclosure Statement on 12/20/06 is acknowledged.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/1/06 and 12/20/06 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejection of record in the previous action not addressed in this office action is withdrawn.

Claim Rejections - 35 USC § 112

Claims 1 , 4-7, 13, 23-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained essentially for the reasons made of record in the previous Office action.

Applicant's arguments filed 11/1/06 have been considered, but have not been found convincing.

Applicant has argued that cell-free extracts are known from a number of bacteria, including "Pseudomonas fluorescens, Staphylococcus aureus, Methanococcus vannielii, Methanobacterium formicicum and Methanosarcina barker, as described in the attached articles and abstracts". However, no such articles and abstracts have been submitted. It is maintained that the preparation of extracts which include vesicles having the respiratory chain components (i.e. mitochondrial membrane vesicles) that are capable of oxidative phosphorylation, as is set forth in the claim presumably in the phrase "oxidative phosphorylation, which is sensitive to electron transport chain inhibitors, is activated in said reaction mix", and which are capable of carrying out in vitro transcription and/or translation, is not described and well known in the art. Therefore, it is maintained that the specification fails to provide a complete written description for the invention as claimed.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4-7, 13, 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable Baranov et al. (Methods in Enzymology, 217, 123-142, 1993) and Chen et al. (Methods in Enzymology, 101, 674-690) (cited for evidentiary purposes only) in view of Yoshida et al. (J. Biol Chem. 274(32), 22723-22728, 1999), Dorner et al. (Proc. Natl. Acad. Sci. USA 76(10):4832-4836, 1979), Shimizu et al. (Nature Biotechnology, 2001, 19 :751-755) (cited by applicants) or Raney et al. (J. Biol. Chem. 275 (32):24444-24450, 2000).

Baranov et al. disclose a method of in vitro synthesis of polypeptides in a reaction mix comprising a biological extract from E. coli grown in glucose containing medium, magnesium at a concentration of from about 5 mM to 20 mM, and substantially free of polyethylene glycol. The reaction mix includes spermidine. See Experiment 5 in Table 1. Note that the E. coli extract is disclosed by Baranov et al. (see page 127, first complete paragraph) as being prepared using a standard method such as that disclosed in Chen et al., Methods in Enzymology, 101, 674-690, in which it is disclosed that the E. coli is grown in medium containing glucose and phosphate (see page 675, lines 7-11). Baranov et al. discloses continuous flow cell free reactions, in which plasmid is added, and transcription (production of mRNA) and translation of the encoded protein result.

The difference between the reference and the instant claims is that batch process is used and spermine or spermidine is present at about1 mM, and the reference does not disclose that oxidative phosphorylation which is sensitive to electron

transport chain inhibitors, or membrane vesicles containing respiratory chain components, are present in the extracts.

However, Baranov et al. disclose that the batch process of cell-free transcription and/or translation is known in the art. While the reference does not explicitly disclose the use of the batch process for the experiment disclosed in Table 1, experiment 5, the reference discloses that such a method is well known in the art and is an alternate technique to method of using continuous flow cell free transcription and/or translation. Furthermore, it is considered that in the absence of evidence to the contrary, membrane vesicles comprising respiratory chain components, and activated oxidative phosphorylation, are present in the reaction mix, since the instant specification discloses using crude S30 extracts from E. coli using standard procedures (page 12), as are used by Baranov et al. (page 127). It would have been obvious to one of ordinary skill in the art to have utilized a batch process of cell free transcription and translation, using the conditions disclosed by Baranov et al., since Baranov et al. disclose that such method was well known and standard practice in the art. One would have been motivated to do so by the well known benefits of ease of practice and simplicity.

In addition, each of Yoshida et al., Dorner et al. Shimizu et al. and Raney et al. disclose in vitro translation systems in which the spermidine is present at a concentration of about 1 mM (see Fig. 4 of Raney et al.; see Table 1 of Dorner et al.; see Figs. 2, 3, 4, of Yoshida et al.; see page 754, second column of Shimizu et al.).

It would have been obvious to one of ordinary skill in the art to have modified the method of in vitro synthesis of polypeptides in a reaction mix by altering the

concentration of spermidine or spermine, including increasing the concentration to about 1 mM, since each of the references Yoshida, Dorner, Shimizu and Raney disclose in vitro translation systems in which varying and increased amounts of spermine and spermidine are present. One would have been motivated to do so by the known effect of spermine and spermidine in in vitro translation, and the known experimental optimization of conditions as disclosed by the references. The references show the state of the art, in which the alteration of the concentration of spermine and spermidine in in vitro translation systems is routine and would have been obvious to one of ordinary skill in the art. Therefore, the invention as currently claimed would have been obvious.

Applicants have argued that Baranov fail to teach the activation of oxidative phosphorylation, and fail to demonstrate an ability to synthesize polypeptides and/or mRNA in the absence of a high energy phosphate source (page 6). However, it is noted that applicants have cancelled language in the claims which recited "the absence of an exogenous high energy phosphate source", and therefore this argument is moot. There is no evidence provided that oxidative phosphorylation is not activated in the reaction mix disclosed by the references. Therefore, applicant's arguments regarding the results obtained in the specification (pages 6-7) are not found convincing. Furthermore, no side-by-side comparisons of the method taught by Baranov et al. and that disclosed in the specification, using identical conditions, such as the protein expressed and time of reaction, has been conducted and therefore it is difficult to

evaluate comparisons of results discussed by applicants. For these reasons, the rejection is maintained.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NV
2/1/07

NANCY VOGEL
PRIMARY EXAMINER